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| 10/748,016 | 12/29/2003 | Vincent P. Bavaro | ACS 66062 (4045X) | 6513 |

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| EXAMINER |
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BRUENJES, CHRISTOPHER P

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| ART UNIT | PAPER NUMBER |
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1772

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/27/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 10/748,016 | Applicant(s) BAVARO ET AL. | |
| | Examiner Christopher P. Bruenjes | Art Unit 1772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 26-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 26-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112, second paragraph rejections of claims 3, 28, 29, 36, 37, 39, and 40 of record in the Office Action mailed November 3, 2006, Pages 4-5 Paragraph 7, have been withdrawn due to Applicant's amendments and arguments in the Paper filed February 5, 2007.

Specification

2. The use of the trademarks PEBAX, PELLETHANE, HYTREL, SANTOPRENE, KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. For more information see MPEP 608.01(v).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1772

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of claim 29 that the radiopaque marker further comprises a coating is not supported by the original specification. The specification teaches adding a coating layer over a guide wire or medical device in which a marker is attached, but there is no support for the marker itself to be coated with a separate coating layer.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the

Art Unit: 1772

invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 24-26, 28, 30, 32-37, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott (US 2003/0164063 A1).

Regarding claims 1-4, 25-26, 32-34, 36-37, the preamble "radiopaque marker" is given little patentable weight for two reasons. First, it appears the preamble is reciting purpose or intended use of the claimed article, which would only be given weight with regard to any structural difference the intended use results in. Second, if the preamble is not merely reciting purpose or intended use the only structural limitation provided by "radiopaque marker" is an article that is opaque to radiation, such as x-rays. This limitation would cover any article as long as it is opaque to radiation. The limitation that the marker is "for a medical device" is given little patentable weight because it is merely an intended use of the marker. Furthermore, the limitation that the marker "have a length, thickness, and cross-sectional size selected for attachment to the medical device . . . flexibility of the medical device" is given little patentable weight. Medical

Art Unit: 1772

devices come in a myriad of different sizes including very small and very large objects. Therefore, to have a length, thickness, and cross-sectional size selected for attachment does not limit the marker to any particular size. Thus, the radiation shield taught by Elliott would have a size that would fall within the claimed limitation. The article of Elliott is a radiation-shielding article (p.3, paragraph 56) and therefore anticipates the structural limitations provided by the preamble. The article of Elliott comprises a polymer such as Pebax and radiopaque particles such as tungsten disposed within said polymer and a wetting agent for facilitating encapsulation of said particles such as a surfactant provided by a wax and a fluoropolymer and/or a coupling agent such as chemically modified polyethylene (p.5, paragraphs 88-93 and Table 2 on p.6). The tungsten has an average diameter of at least 2 microns and a maximum diameter of about 20 microns, as shown by the particle size distribution (p.6, paragraph 94). The radiopaque particles include greater 93.9 weight percent of the composite (Table 2 on page 6).

Regarding claims 24 and 35, the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94).

Art Unit: 1772

Regarding claims 28-30, 39, and 40, the limitations that the marker is a coating or attached to a medical device are intended use functional limitations of the radiopaque marker. The marker is an article and articles are defined by there structure not merely what the article is used for or how it is made. The functional limitations of these claims do not add further structural limitations to the marker, so they are given little patentable weight. The composite of Elliott has the ability to be used in the forms claimed, therefore the composite anticipates the claim. See MPEP 2114.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1772

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 5, 27, 31, and 38 are rejected under 35 U.S.C.

103(a) as being unpatentable over Elliott (US 2003/0164063 A1).

Regarding claim 5, Elliott teaches all that is claimed in claim 1 as shown above, and teaches that the article is manufactured as a radiation shield. Elliott fails to teach that the article is necessarily formed to define a tubular structure. However, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that depending on the shape of the object the article of Elliott is providing a radiation shield to would determine the shape of the article of Elliott.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiation shield of Elliott to define a tubular structure when the object shielded from radiation has a tubular shape.

Regarding claims 27 and 38, Elliott teaches all that is claimed in claims 1 and 32 as shown above, but fail to teach that the article further comprises an antioxidant. However, it

Art Unit: 1772

is well known in the art that antioxidants are added to elastomers in order to improve prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the article of Elliott, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claim 31, although what the medical device is with regard to the marker is given little patentable weight because it is merely further defining an intended use of the claimed marker, this limitation adds at least some type of maximum size requirement to the size limitations in claim 1. Specifically, the marker in claim 31 is required to have a length, thickness, and cross-sectional size selected for attachment to a stent, guide wire, balloon, or embolic filter, which are all relatively small articles. However, there is still no specific size requirement and Elliott teaches many

Art Unit: 1772

different types of articles having different sizes, so it would be obvious to one having ordinary skill in the art at the time Applicant's invention was made the article of Elliott would be formed with the length, thickness, and cross-sectional size desired for the intended end result of the desired article produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the length, thickness, and cross-sectional size that would be sufficient for attachment to a stent, guide wire, balloon, or embolic filter, depending on the intended end result of the article, since Elliott teaches many different sized articles.

Response to Arguments

10. Applicant's arguments regarding the 35 U.S.C. 112, first paragraph rejection of claim 29, have been considered but they are not persuasive.

In response to Applicant's argument that the specification teaches that the marker is formed by extrusion coating, the Examiner agrees with this point. However, claim 29 is not claiming that the marker is made by a coating process, claim 29 is claiming that a coating is applied to the marker. The marker

Art Unit: 1772

is described throughout the specification as being of a single substance and being a coating itself, the specification does not mention that the marker contains a further coating.

11. Applicant's arguments regarding the 35 U.S.C. 112, second paragraph rejections of claims 3, 28, 29, 36, 37, 39, and 40, have been considered but they are moot since the rejections have been withdrawn.

12. Applicant's arguments regarding the 35 U.S.C. 102 and 103 rejections of claims 1-5 and 24-40 over Elliott have been fully considered but they are not persuasive.

In response to Applicant's argument that Elliott fails to teach that the article has the length, thickness, and cross-sectional size claimed, the claimed length, thickness, and cross-sectional size includes almost every length, thickness and cross-sectional size. The claim only requires that the size be selected for attachment to a medical device. Medical devices come in a vast range of sizes that would include articles large enough for any of the articles taught by Elliott to be the correct size to attach. Furthermore, beyond the size limitation itself the rest of the added limitations only add intended use or functional limitations to the marker, which are only given

Art Unit: 1772

weight insofar as the structure required to have the capability to perform the functions. None of the added functional limitations require any additional structure beyond what is already claimed in claims 1 and 32.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

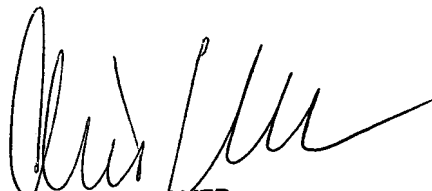
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher P Bruenjes
Examiner
Art Unit 1772
CPB
April 18, 2007


ALICIA CHEVALIER
PRIMARY EXAMINER